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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/642,638 | 08/19/2003 | Howard R. Levin | 3659-70 | 3724 |

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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3761 | |

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/642,638 | LEVIN ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *56-65,67-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *56-63* is/are allowed.

6)☒ Claim(s) *64,65 and 67-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 March 2006 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims, 64, 65, and 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over a disclosure of the Hospal Miniflow 10 (see pages of internet data, accompanied by 1997 study from Gouyon et al, showing the existence of the Miniflow 10 as early as 1997), in view of US 5,246,582 to Sluma et al.

With regard to claims 64, 65, 67, and 70, the Miniflow is disclosed and shown as having a hollow fiber surface area below $0.1m^2$, blood input and output lines with pump, and dialysis input and output lines with pumps (see CVVD illustration). The hollow fibers are arranged in a bundle in a straight housing (see diagram). The documentation does not disclose the dimensions of the housing, but the Miniflow appears to be less than

20cm long and less than 1.5cm in diameter. The Miniflow is also disclosed as being capable of use within a hemodialysis procedure, including the steps of flowing blood through the filter membrane in countercurrent to a dialysis fluid (see Hospal page entitled "Pump-assisted renal replacement therapies). As such, the Hospal filter apparatus has a filter membrane surface comprising the interior of the hollow fibers.

With regard to applicant's claim language drawn to the volume of the container comprising less than 2% of the patient's cardiac output, such a size limitation comprises an obvious variation of the device. See MPEP 2144.04. In the instant case, the Hospal cartridge is capable of holding less than 2% of a patient's cardiac output, since patients of various size, and corresponding various blood volume and cardiac output, may be treated by the device.

The Miniflow documentation does not disclose the molecular weight of the molecules filtered, but Sluma discloses a filtration membrane that may have a screening coefficient for molecules of approximately 50,000 Daltons. The filter membrane is made with such small pore sizes in order to facilitate ultrafiltration (see column 3, lines 45-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow-fiber filter membranes of the Hospal Miniflow 10 to block passage of molecules of about 50,000 Daltons as disclosed by Sluma in order to provide ultrafiltration, as taught by Sluma.

With regard to applicant's claim 69 drawn to the number of hollow fibers in the filter cartridge, it has been held that the duplication of the essential working parts of a device (in the instant case, a plurality of hollow fiber filters) involves only routine skill in

the art. See MPEP 2144.04. In the instant case, applicant has not shown that any particular number of hollow fibers solves any stated problem or is for any particular purpose. It appears that the device would function equally well with the number of fibers claimed by applicant or the number of fibers disclosed by the prior art. Therefore, such a change in the number of hollow fibers is considered by the examiner to be an obvious variation on the prior art.

Similarly, applicant's claims 68 and 71 comprise limitations drawn to the length of the fibers and the diameter of the fiber bundle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the size of the Miniflow to the dimensions desired by applicant since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04. . In the instant case, applicant has not shown that any particular length or diameter of the hollow fiber bundle solves any stated problem or is for any particular purpose. It appears that the device would function equally well with the hollow fiber bundle dimensions claimed by applicant or the dimensions disclosed by the prior art. Therefore, such a change in the dimensions of the hollow fiber bundle is considered by the examiner to be an obvious variation on the prior art.

***Allowable Subject Matter***

4. Claims 56-63 are allowed.

5. The following is a statement of reasons allowance: The prior art fails to disclose or suggest the methods as claimed by applicant.

With regard to the independent claims, the prior art fails to suggest a method of ultrafiltration comprising the combination of the steps of withdrawal and return of blood to a patient while utilizing a filter membrane with the claimed surface area and claimed porosity, wherein the filtrate and/or the blood is moved through the filter cartridge at the rates and within the times claimed by applicant, along with the other steps and limitations of the claims.

***Response to Arguments***

6. Applicant's arguments filed 30 March 2006 have been fully considered but they are not persuasive.

7. Applicant argues that the Hospal Miniflow 10 is designed for use with neonates and infants, and processing less than 2% of the cardiac output of such small patients would result in a flow rate that is below the disclosed operating parameters of the Miniflow 10. However, it is the position of the examiner that the Miniflow 10 is not limited to use with neonates and infants. The device may be deployed for use with adult patients, who have a higher total cardiac output, resulting in a flow rate that falls within the disclosed parameters of the Miniflow 10.

Applicant's recitation that the volume of the blood passage in the filter is "less than two percent of a cardiac output of the patient" does not sufficiently define a particular volume that is excluded by the Miniflow 10. It is the position of the examiner that the size of the patient determines the cardiac output, and there is some patient for whom the Miniflow 10's blood volume comprises less than two percent of the cardiac output of that particular patient.

Since the Miniflow 10 is capable of providing a blood passage volume that is less than two percent of the cardiac output of a patient, it meets the limitations of the claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
21 November 2006